Safe Medication Dispensing: Using an Integrated Approach with the Patient and Health Care Team

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Midwest Medication Safety Symposium

Indiana University Health

Disclosure

- I have no financial disclosure or conflicts of interest in relation to this program/presentation.

Objectives:

- Recognize the need for developing a safe medication dispensing policy
- Identify areas to standardize in reviewing opioid prescriptions
- Describe how to escalate or have difficult conversations around inappropriate use or prescribing

The Opioid Epidemic[5,20,22]

- In 2017 HHS declared the opioid epidemic a public health emergency
- More than 232,000 died from prescription opioid overdoses from 1999-2018
  - Totals in 2018 were more than four times greater than in 1999
- The Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement

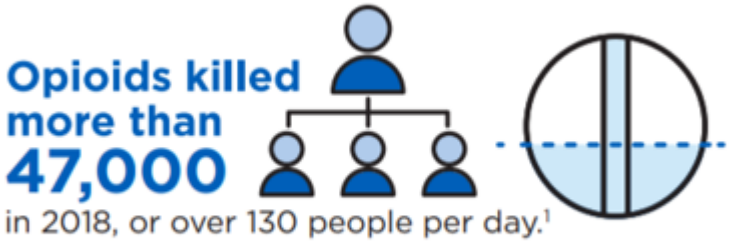


Figure 1. **CMS Roadmap Strategy to Fight the Opioid Crisis** CMS, released June, 2020. Retrieved from https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.

The Opioid Epidemic[5,20]

- Prescription opioids
  - Between 8 and 12 percent of patients develop an opioid use disorder
  - Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them
  - An estimated 4 to 6 percent of individuals who misuse prescription opioids transition to heroin
  - Over 200 million opioids are dispensed from community pharmacies annually since 2008

Figure 1. **CMS Roadmap Strategy to Fight the Opioid Crisis** CMS, released June, 2020. Retrieved from https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.

The Opioid Crisis[4,18]

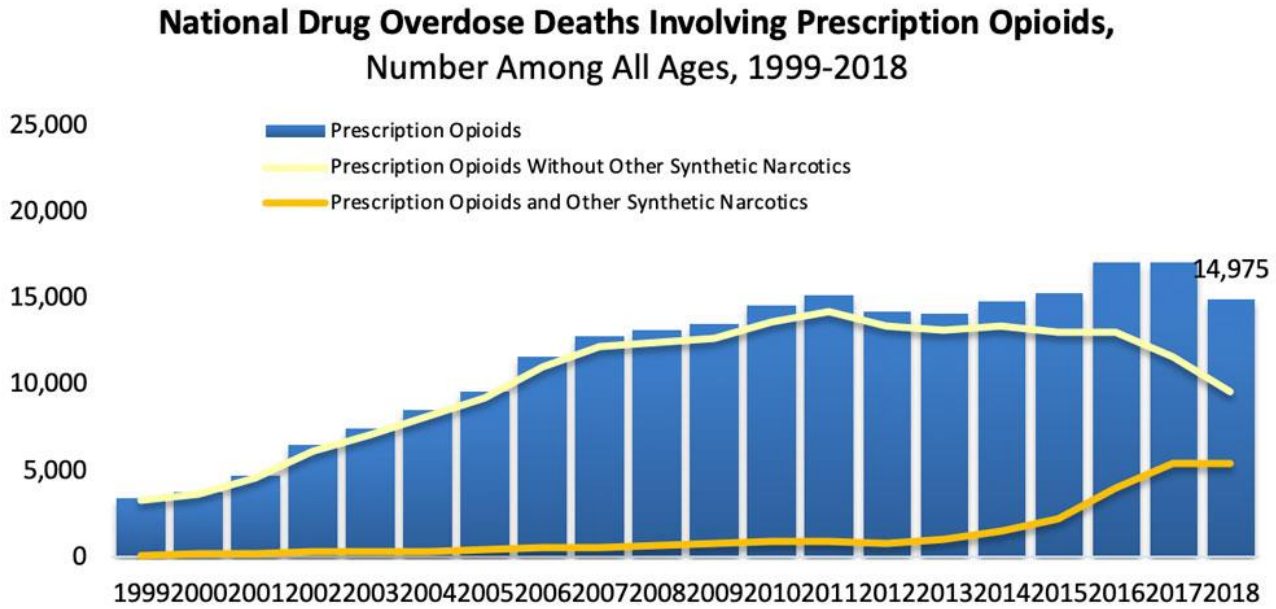
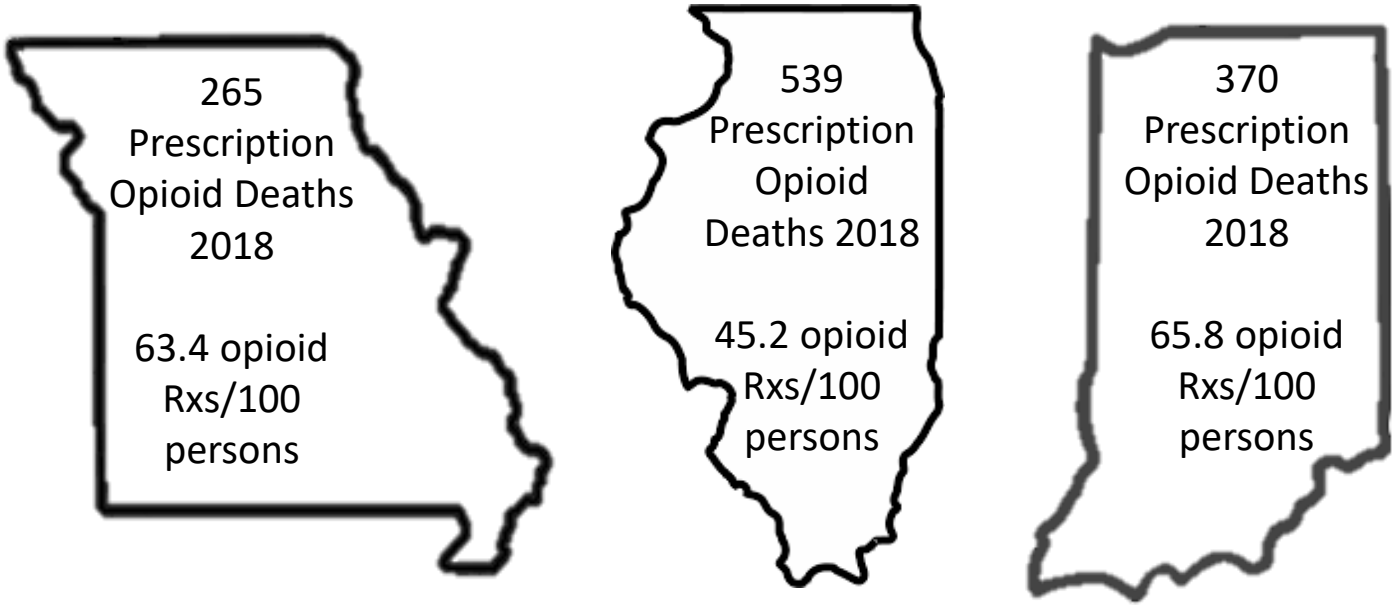


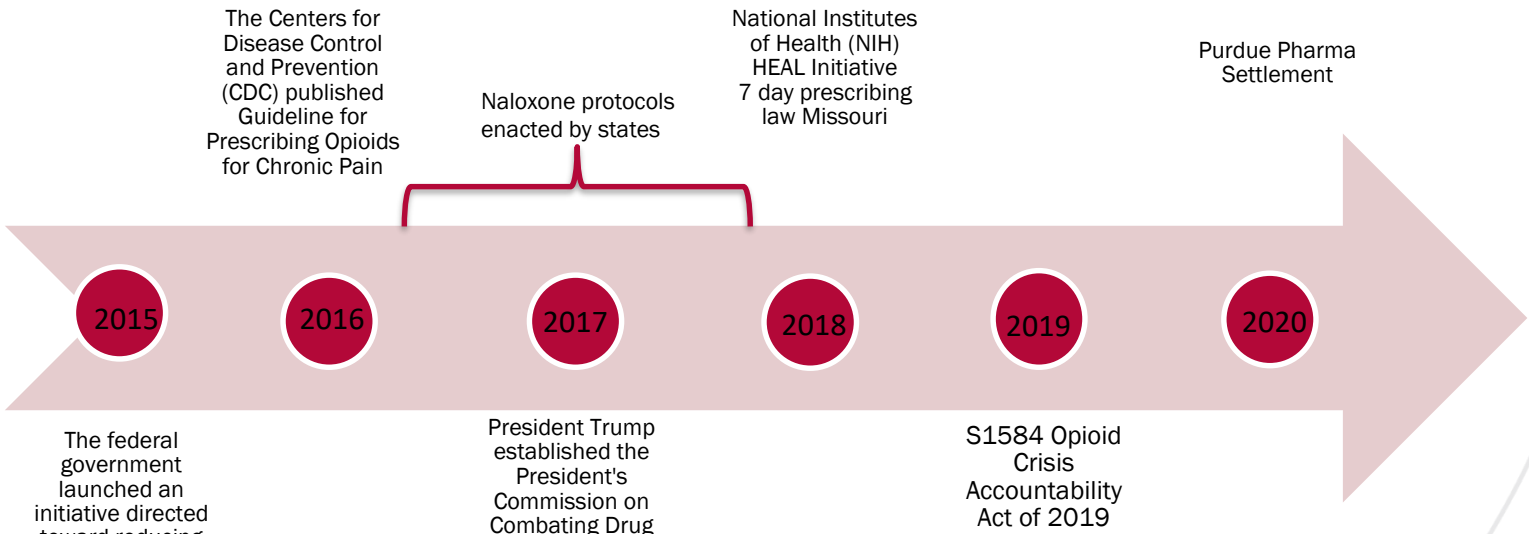
Figure 1. **National Overdose Deaths Involving Prescription Opioids—Number Among All Ages, 1999-2018** CDC WONDER Online Database, released January, 2020. Retrieved from www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates.

Midwest Impact[19,21]



- Average U.S. rate was 51.4 prescriptions/100 persons

Actions to Combat the Epidemic[7,9,16,20,22]



Actions to Combat the Epidemic

- Prescribing Guidelines
- Prescription Drug Monitoring Programs (PDMPs)
- Pharmacy Benefit Managers (PBMs) and Pharmacies
- Engineering Strategies
- Overdose Education and Naloxone Distribution Programs
- Addiction Treatment
- Community-Based Prevention

States with laws limiting opioid prescriptions and requiring the use of prescription drug monitoring programs as of April 2018[1,8,10]

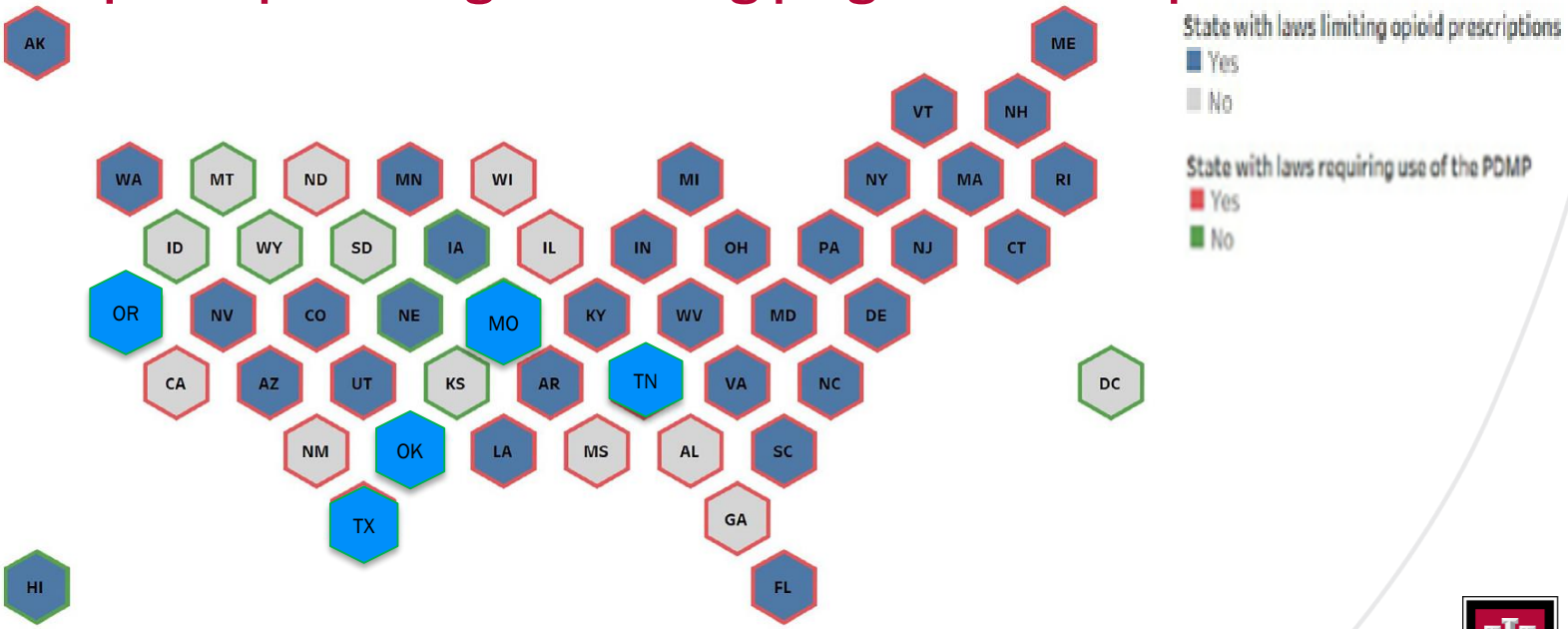


Figure 1. From *The National Conference of State Legislatures (as of April 5, 2018) and the Prescription Drug Monitoring Program Training and Technical Assistance Center (as of March 19, 2018)*. Retrieved from https://www.clinicalkey.com/#!/content/playContent/1-s2.0-S0749379718318658?returnurl=https:%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0749379718318658%3Fshowall%3Dtrue&referrer=https:%2F%2Fpubmed.ncbi.nlm.nih.gov%2F

Last Lines of Defense[1,9,10]

1. Providers
   - The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain
     - Mobile applications
     - Continuing education
   - Clinical practice guidelines/policies to promote safer, more effective chronic pain treatment
   - State regulations
   - PDMP requirements
- Impact
   - Some declines in opioid prescribing rates and high-dose prescribing (≥90 MME)
   - Provider wariness to prescribe opioids at all

Last Lines of Defense[2,13,15,17,23]

2. Pharmacists

- Presentation of Rx:
  - Evaluate authenticity- Identify prescription falsifications or alterations and serve as the first line of defense in recognizing problematic patterns in prescription drug use
  - Look for red flags
- Filling of the prescription
  - Use PDMPs to help track opioid-prescribing and dispensing patterns in patients
  - Contact prescriber
- Dispensing
  - Help patients understand instructions for taking their medications along with how the medication works
  - Educate, warn about risks
  - Naloxone information
- Corresponding responsibility to make sure the prescription is valid and for a true medical purpose.

Corresponding Responsibility[23]

- Title 21 Code of Federal Regulations
- PART 1306 — PRESCRIPTIONS
- **§1306.04 Purpose of issue of prescription.**
- (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (**21 U.S.C. 829**) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Last Lines of Defense[13,15]

- Impact
  - Drug take back boxes
  - Naloxone dispensing
  - Development of pharmacy policies (Chain specific)
    - Good Faith Dispensing
    - Red Flag Rules
    - Limited quantities or refusal to fill
  - Confusion of roles and responsibilities

Last Lines of Defense[24]

Walmart has sued the U.S. Department of Justice (DOJ) and the Drug Enforcement Administration (DEA), asking a federal court to clarify the roles and responsibilities of pharmacists and pharmacies under the Controlled Substances Act (CSA). *Walmart Inc. v. DOJ, et al*. is pending before the U.S. District Court for the Eastern District of Texas.

Last Lines of Defense[6,17]

3. Payers

- Create coverage policies to improve pain management and reduce opioid-related injuries and deaths
- Share strategies, such as reimbursement and coverage policies, conditions for provider plan participation
- Share information to a variety of audiences due to relationships with providers, pharmacies, patients, employers, and law enforcement
- Identify trends with access and analysis of data

- Impact:
  - Limited day supplies or quantities
  - Limiting morphine milligram equivalents (MME)
  - Prior Authorizations for chronic medications
  - Identifying opioids and other medications (benzos, etc)
  - Real time safety edits
  - Restricted or ‘lock in’ pharmacies

Patient Impact[3,11,22]

- Patients experienced:
  - Loss of access to opioid medications
  - Fear of losing access to medications
  - Inability to find a doctor
  - Stigma from providers and pharmacies

Safe Medication Dispensing[14]

- A policy to:
  - Protect and empower pharmacists
  - Create collaboration with providers and patients
  - Address the pharmacist's corresponding responsibility
- No exclusions were included
- A Safe Dispensing Medication list was created to include opioids and any medications of concern
- Provided additional requirements beyond validating authenticity of a prescription and common 'red flags'

Safe Medication Dispensing[14]

IU Health Retail Pharmacy Network
Safe Dispensing Medication List

Generic Name	Common Brand Name Products
Codeine *	Cheratussin AC; Virtussin AC; G Tussin AC; Tylenol w/ Codeine #3 and #4
Fentanyl	Duragesic; Fentora; Lazanda; Subsys
Hydrocodone *	Hycet; Lorcet; Lortab; Norco; Vicodin; TussiCaps; Hydromet
Hydromorphone	Dilaudid
Methadone	Methadose; Dolophine
Morphine *	MS Contin; Kadian; Avinza; Mitigo; Morphabond ER
Tapentadol	Nucynta
Oxycodone*	Oxycontin; Roxicodone; Xtampza ER; Endocet; Percocet
Oxymorphone	Opana
Tramadol *	Ultram; Ultracet

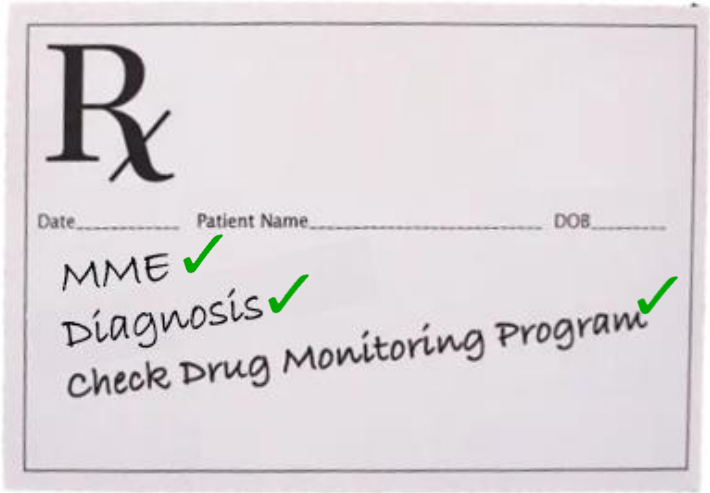
* Includes all formulations including, but not limited to, ER, IR and combination medications.

Red Flags[9,23]

- Pattern prescribing (i.e. prescriptions for the same drugs and the same quantities from the same doctors)
- Irregularities on the face of the prescription itself
- Nervous patient demeanor
- Multiple or duplicative therapies (i.e. Oxycontin and MS Contin)
- Prescribing of combinations or “cocktails” of frequent abused controlled substances
- Geographic anomalies
- Shared Addresses
- Filling a larger percentage of cash prescriptions
- Customers with the same diagnosis code from the same doctor
- Prescriptions written that are not consistent with their area of specialty
- Prescriptions for medications with no logical connection to diagnosis or treatment
- Consistent requests for early refills
- Refilling prescriptions of patients or doctors located hundreds of miles away

Safe Medication Dispensing[14]

- On every safe dispensing prescription:
  - Review for authenticity
  - Calculate and document Milligram Morphine Equivalent (MME)
  - Document diagnosis
  - Complete and document PDMP check

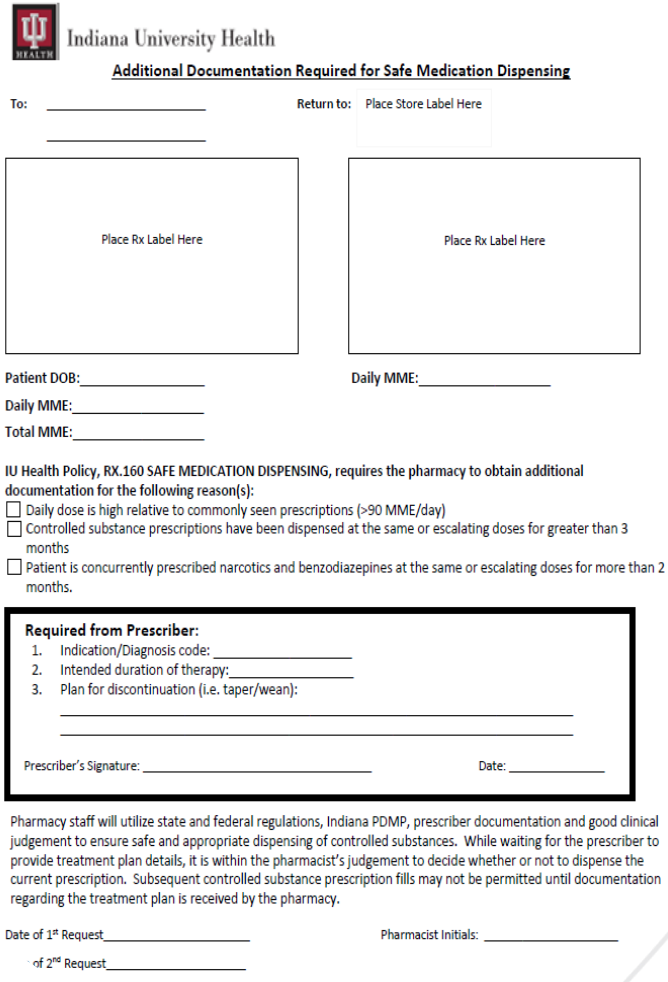


Safe Medication Dispensing[14]

- Pharmacists shall contact the prescriber or utilize electronic medical record documentation to obtain a treatment plan if:
  1. Daily dose exceeds 90 MME/day limit trigger, or
  2. Medications on the Safe Dispensing List have been dispensed at the same or escalating doses for greater than 3 months, or
  3. Patient is concurrently prescribed medications on Safe Dispensing List and benzodiazepines at the same or escalating doses for more than 2 months.
  4. Treatment plans are not required for acute prescriptions.

Safe Medication Dispensing[14]

- Treatment plan information should include the following:
  - Indication(s)
  - Intended duration of therapy
  - Plan for eventual discontinuation (taper) or documentation of why a patient may require chronic therapy



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Additional Documentation Required for Safe Medication Dispensing

To: _____ **Return to:** Place Store Label Here

_____

Place Rx Label Here

Place Rx Label Here

Patient DOB:_____ **Daily MME:**_____

Daily MME:_____

Total MME:_____

IU Health Policy, RX.160 SAFE MEDICATION DISPENSING, requires the pharmacy to obtain additional documentation for the following reason(s):

☐ Daily dose is high relative to commonly seen prescriptions (>90 MME/day)

☐ Controlled substance prescriptions have been dispensed at the same or escalating doses for greater than 3 months

☐ Patient is concurrently prescribed narcotics and benzodiazepines at the same or escalating doses for more than 2 months.

Required from Prescriber:

1. Indication/Diagnosis code: _____
2. Intended duration of therapy:_____
3. Plan for discontinuation (i.e. taper/wean):

_____

_____

Prescriber's Signature: _____ Date: _____

Pharmacy staff will utilize state and federal regulations, Indiana PDMP, prescriber documentation and good clinical judgement to ensure safe and appropriate dispensing of controlled substances. While waiting for the prescriber to provide treatment plan details, it is within the pharmacist's judgement to decide whether or not to dispense the current prescription. Subsequent controlled substance prescription fills may not be permitted until documentation regarding the treatment plan is received by the pharmacy.

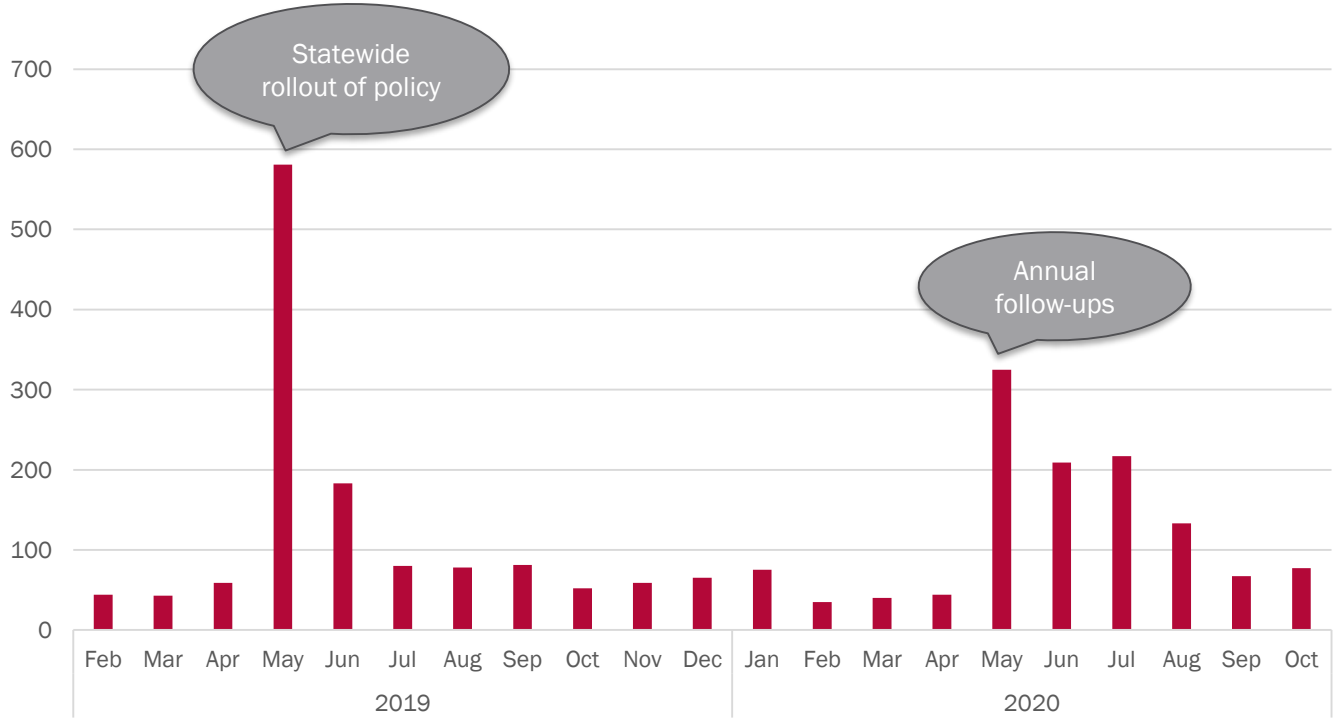
Date of 1st Request_____ Pharmacist Initials: _____

of 2nd Request_____

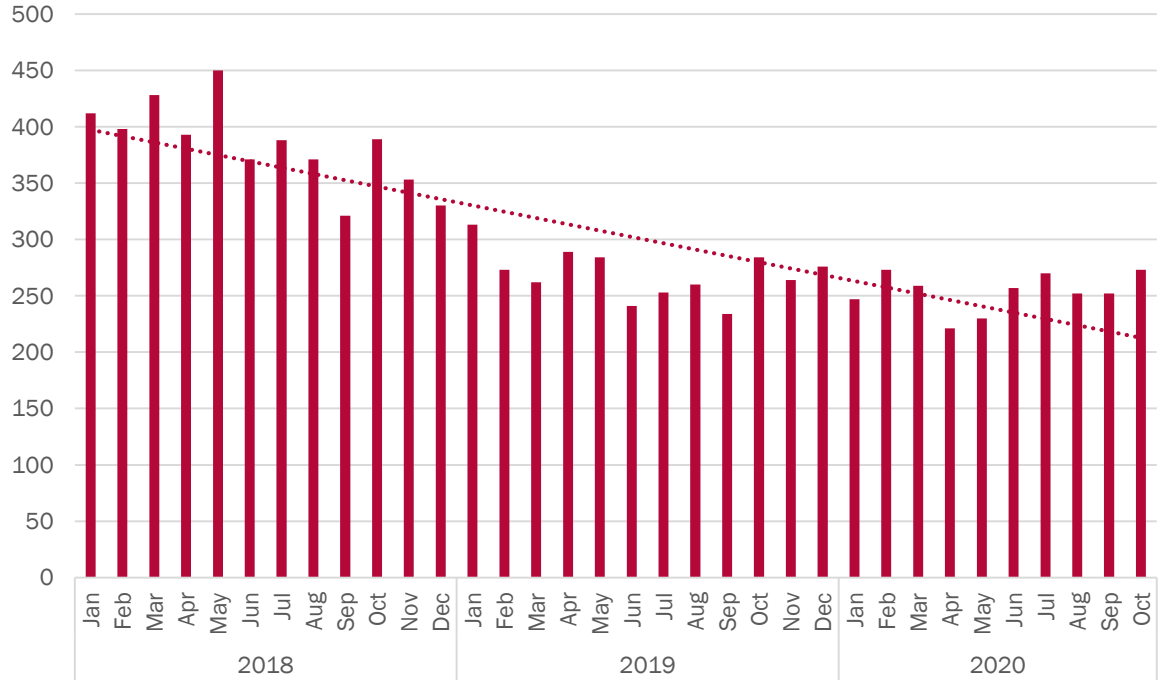
Safe Medication Dispensing[6,9]

- Why 90 MME?
  - The threshold of 90MME or greater is referenced in the CMS opioid provider letter as the **Opioid care coordination alert**: This is an alert for pharmacists to review when the patient's cumulative morphine milligram equivalents (MME) reaches 90 mg or greater per day
  - CDC opioid prescribing guidelines state: Clinicians should avoid increasing opioid dosages to ≥90 MME/day or should carefully justify a decision to increase dosage to ≥90 MME/day based on individualized assessment of benefits and risks
  - This 90 MME threshold identifies potentially high risk patients who may benefit from closer monitoring and care coordination. In reviewing the alert, the pharmacist may contact the prescriber to confirm medical need for the higher MME. The pharmacist may talk with the prescriber about other opioid prescribers or increasing level (MME) of opioids. After that discussion to confirm intent, the pharmacist can fill the prescription.

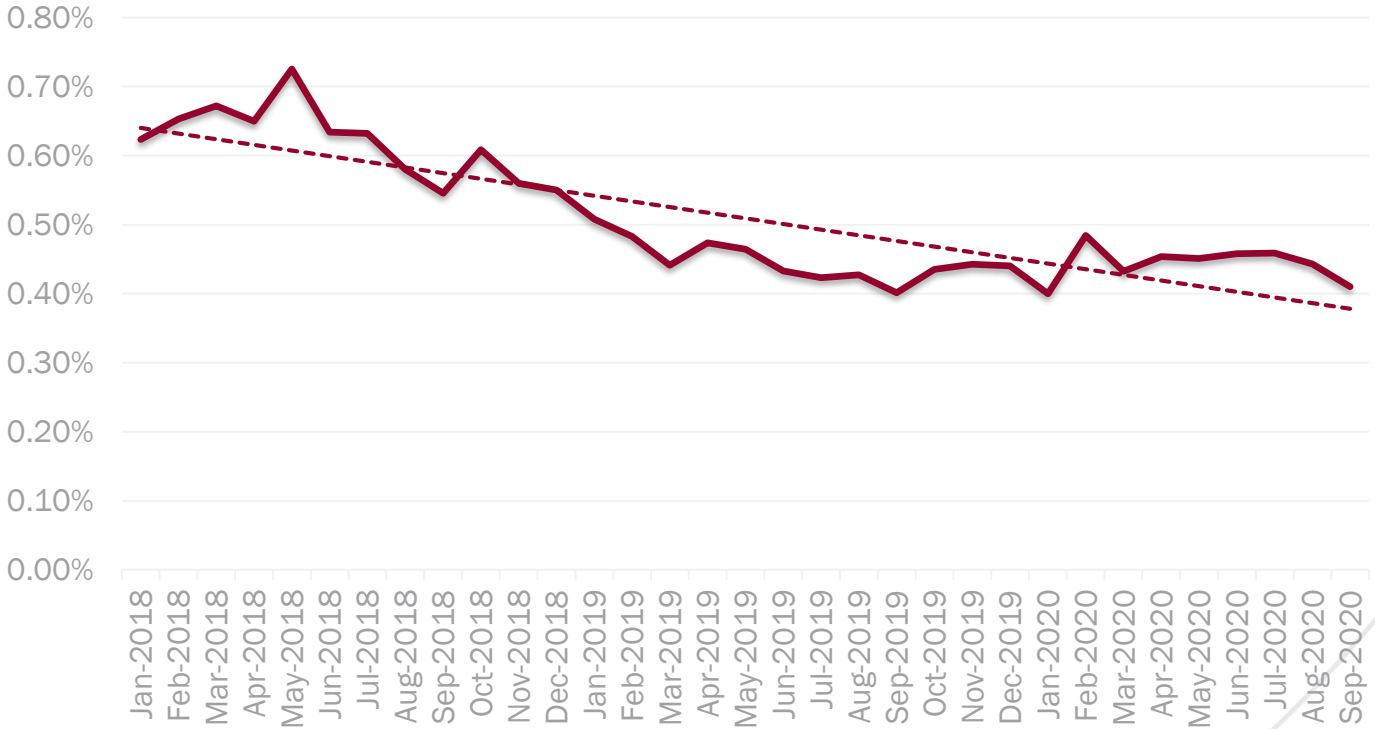
Safe Dispensing documents sent by month



Total Prescriptions >90 MME



Number of prescriptions >90 MME as a percentage of total volume by month



Difficult Conversations[8,9,12,13,17]

- Providers
  - CVS Caremark instructed pharmacists to reach out by phone to communicate the edit or rejection and discuss whether the quantity could be reduced.
  - Provider acceptance regarding feedback on patient behaviors
  - The American Medical Association warned against the practice of routine pharmacist prescription diagnosis verification
  - Professional pharmacy organizations call for more effective communication and collaboration between pharmacists and physicians

Figure 1. Embedding Pharmacists Into the Practice. AMA Released 2018. Retrieved from https://edhub.ama-assn.org/steps-forward/module/2702554.

Difficult Conversations[11,1]

- Patients
  - Misunderstand the role of the pharmacist
    - Medication Safety
      - **Directions**
      - **Appropriate use**
      - **Storage and disposal**
      - **Appropriate prescribing**
      - **Medical need**
      - **Naloxone**

Success stories

- Successful planning and partnership with several IUH doctors who have embraced the process and have began to adjust therapies and wean/taper patients who otherwise might have continued on current regimens that might have been excessive.
- Weed out a handful of patients/docs who simply could not or would not provide documentation supporting pain regimens.
- Empowered pharmacists
- Collaboration with system pharmacies
- Collaboration with providers
- Support from the health care system

Lessons learned

- Consider clear definitions acute vs. chronic
- Consider clear instructions for documentation & follow up
- Utilize consistent tools (MME calculator)
- Consider difficult conversations and when to draw the line
- Utilize technology – Narxcare
- Engage the whole system

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